Keeping up with NIH rules impacting research involving human subjects

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The National Institutes of Health (NIH) made a number of changes to the rules impacting research involving human subjects in recent years, including the launch of several new initiatives that fall into two categories: those that affect all research involving human participants and those that only affect research that meets the NIH definition of a clinical trial.

Changes that affect all research involving human participants include the use of new forms to collect human subject information and the requirement to use a single Institutional Review Board for multi-site studies. Both changes went into effect on January 25, 2018. The NIH also now requires Certificates of Confidentiality for all research ongoing after December 13, 2016, that uses identifiable data, bio-specimens or genomic data. A Certificate of Confidentiality is automatically issued to qualifying research and requires researchers to protect the privacy of individual research subjects.

For NIH purposes, clinical trials are research studies in which human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Recent changes affecting clinical trials, effective January 25, 2018, include new review criteria

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questions highlighting the study's rationale and design to ensure that key information is submitted with each application. Reviewers must appropriately consider this information to ensure the highest likelihood of translating research results into knowledge that will improve human health. Also effective January 25, 2018, all applications proposing clinical trials must be submitted through a Funding Opportunity Announcement to improve NIH's ability to identify proposed clinical trials and uniformly apply the review criteria. The NIH's broad definition of clinical trial means these new requirements affect a large range of research projects. Additionally, as of January 2017, all NIH-funded clinical investigators and staff are required to be trained in Good Clinical Practice (GCP) and must retake the GCP training every three years. Expanded registration and results reporting requirements for the public online repository, ClinicalTrials.gov, also went into effect on January 1, 2017.

Entities that participate in NIH-funded research need to stay up to date on all requirements to ensure compliance with conditions of the grants.